Gambro Renal Products
10810 West Collins Avenue
Lakewood, CO 80215

5.0 510(K) SUMMARY

JAN 3 0 2007

Submitter's Name	Gambro Renal Products
Address	10810 West Collins Avenue Lakewood, CO 80215
Establishment Number	1713683
Date of Submission	October 31, 2006
Contact Person	Thomas B. Dowell, Regulatory Affairs Project Manager
Telephone Number **Fax Number**	(303) 231-4094 (303) 542-5138
Name of the Device	Gambro QuickSet® Bloodlines
Catalogue Numbers	018430501: Gambro QuickSet® Post-pump arterial chamber 018440501: Gambro QuickSet® No arterial pressure monitoring 009445601: Gambro QuickSet® No arterial pressure monitoring 009558601: Gambro QuickSet® Pre-pump arterial chamber 009559601: Gambro QuickSet® Post-pump arterial chamber 009566601: Gambro QuickSet® Pre-pump pillow with post arterial chamber 009558714: Gambro QuickSet® Pre-pump arterial chamber 009566714: Gambro QuickSet® Pre-pump pillow with post arterial chamber
Common or Usual Name	Extracorporeal blood circuit for hemodialysers
Classification Name	Classification Name: Hemodialysis system and accessories Device Class: II Product Code: FJK Regulation Number: 21 CFR 876.5820
Identification of the Legally Marketed Device (Predicate Device)	Gambro G Series Bloodline Sets for Hemodialysis Cobe Hemaflo™ Blood Tubing Sets

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510(k) SUMMARY, continued

Device Description

The Gambro medical lines QuickSet® are tubing sets (bloodlines) employed in the hemodialysis equipments extracorporeal circulation: they convey the patient's blood from the arterial-venous access fistula to the dialyzing filter (arterial line) and back after purification (venous line). The Gambro Medical lines QuickSet® Bloodlines are single use sterile medical devices intended to provide extracorporeal blood circuit for hemodialysis treatment. QuickSet® Bloodlines can be safely connected to hemodialyzers, vascular accesses and various perfusion lines, under the responsibility of the physician in charge.

Comparison Table

	PREDICATE G Series Blood Line	**PREDICATE** Hemaflo™ Blood Tubing Set	**MODIFIED DEVICE** QuickSet® Bloodlines [currently distributed]	**MODIFIED DEVICE** QuickSet® Bloodlines [new models]
Indication for Use	The Gambro G series blood lines are intended for use during hemodialysis in conjunction with an artificial kidney (hemodialyzer). The type of blood line for use is dependent upon the type of dialysis delivery system employed.	Cobe Hemaflo™ Disposable Blood Tubing Set is intended for use in hemodialysis treatment.	The Gambro Medical lines QuickSet® Bloodlines are single use sterile medical devices intended to provide extracorporeal blood circuit for hemodialysis treatment. QuickSet® Bloodlines can be safely connected to hemodialyzers, vascular accesses and various perfusion lines, under the responsibility of the physician in charge.	The Gambro Medical lines QuickSet® Bloodlines are single use sterile medical devices intended to provide extracorporeal blood circuit for hemodialysis treatment. QuickSet® Bloodlines can be safely connected to hemodialyzers, vascular accesses and various perfusion lines, under the responsibility of the physician in charge.
Currently in Distribution	**NO**	**NO**	**YES**	**NO**

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	PREDICATE G Series Blood Line	**PREDICATE** Hemaflo™ Blood Tubing Set	**MODIFIED DEVICE** QuickSet® Bloodlines [currently distributed]	**MODIFIED DEVICE** QuickSet® Bloodlines [new models]
Catalogue No.	Not applicable	Not applicable	009445601 009558601 009559601 018430501 018440501 009566601	009558714 009566714
Arterial Chamber	Injection Molded	Injection Molded	Blow Molded	Injection Molded
Venous Chamber	Injection Molded	Injection Molded	Blow Molded	Injection Molded
Clamps	Pinch & Slide	Slide	Pinch	Pinch
Blood tubing material	Soft PVC material with DEHP plasticizer	Soft PVC material with DEHP plasticizer	Soft PVC material with DEHP plasticizer	Soft PVC material with DEHP-free plasticizer
Injection plug material	Latex	Latex	Latex-free (SEBS)	Latex-free (SEBS)
Packaging	Blister	Pouch	Pouch	Blister
Quantity per box	16	10	16	14
Sterilization Method	ETO	Radiation	Radiation	Radiation
Expiration	3 years	3 years	3 years	3 years
Single Use	Yes	Yes	Yes	Yes
Storage Temperature	Between 10°C (50°F) and +24°C (75°F)	Between 10°C (50°F) and +24°C (75°F)	Between 0°C (32°F) and +30°C (86°F)	Between 0°C (32°F) and +30°C (86°F)

Description and Conclusion of Testing

Nonclinical Testing:
The non-clinical testing consisted of performance testing (bench) that included biocompatibility testing, validation of the sterilization process, sterility testing, flow rate testing, validation of needle and needle-less system injection ports, compatibility testing with different hemodialysis machines, and testing for mechanical hemolysis.

Conclusion:
The successful non-clinical testing demonstrates the safety and effectiveness of the Gambro QuickSet® Bloodlines when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Thomas B. Dowell
Regulatory Affairs Project Manager
GAMBRO Renal Products
10810 West Collins Avenue
LAKEWOOD CO 80215

JAN 3 0 2007

Re: K063290
Trade/Device Name: Gambro QuickSet® Bloodlines
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FJK
Dated: October 31, 2006
Received: November 1, 2006

Dear Mr. Dowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063290

Device Name: Gambro QuickSet® Bloodlines

Indications for Use:

The Gambro Medical lines QuickSet® Bloodlines are single use sterile medical devices intended to provide extracorporeal blood circuit for hemodialysis treatment. QuickSet® Bloodlines can be safely connected to hemodialyzers, vascular accesses and various perfusion lines, under the responsibility of the physician in charge.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063290